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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,660	12/08/2000	Haruhiko Kouhara	038602/1023	1711

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,660

Applicant(s)

KOUHARA ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-6,11-13 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,11-13,20,21 and 23 is/are allowed.
- 6) ☒ Claim(s) 4-6,22 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment of claims 11, 21 and 22 and the addition of new of claims 24-29, the paper of 11/10/2003, is acknowledged. Claims 2, 4-6, 11-13 and 20-29 are at issue and are present for examination. Applicants arguments presented on 11/10/2003,, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claim 27 is objected to because of the following informalities:

Newly added claim 27 ends with a semi-colon rather than a period.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly added claim 27 is indefinite in the recitation "...regulates growth factor stimulation of cellular differentiation and cellular proliferation". While applicants point to applicants specification at page 5, lines 20-22 for support for such a functional

description, the phrase is vague and confusing because it remains what is encompassed by such a limitation. It is acknowledged that the "regulation of growth factor stimulation of cellular differentiation and cellular proliferation" may occur in a number of different ways, such as transcriptionally, translationally and post-translationally which includes phosphorylation, yet applicants have not defined what is encompassed by the recited limitation in the claim and thus the claim is indefinite.

Newly added claim 25-29 are each indefinite in that they each are drawn to the isolated nucleic acid molecule of claim 11 wherein each claim then adds additional limitations of the claimed molecules. Applicant is reminded that claim 11 is drawn to nucleic acid molecule comprising a nucleotide sequence that encodes the full length amino acid sequence of SEQ ID NO: 1. Each of the additionally added limitations of claims 25-29 attempt to modify the nucleic acid of claim 11 such that it no longer would be the nucleic acid of claim 11. Thus each of the se claims are indefinite in that they are vague and confusing. For example claim 25 limits the claimed nucleic acid of claim 11 (which encodes SEQ ID NO: 1) such that it lacks at least one segment of SEQ ID NO: 1. This is inconsistent and not possible. If it is SEQ ID NO: 1, then it must be SEQ ID NO: 1, not SEQ ID NO: 1 minus residues 1-10. Claims 26-29 are similarly confusing and unclear. It is noted to applicants that claims 25-29 are interpreted as being drawn to the nucleic acid having each of the limitations corresponding with each of the respective claims (i.e. not including the limitation of claim 11 from which they depend).

Art Unit: 1652

Claim 29 part (a) which is drawn to a polypeptide as set forth in claim 11 (a), 25 (a) or 28 (a) is unclear and confusing for similar reasons as discussed immediately above for claims 25-29.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6, 22, 24 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applied to claims 2, 4-6 11-13 and 20-23. In response to the previous office action applicants have amended claims 11, 21 and 22 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection on the basis that applicants specification discloses that a nucleic acid can encode at least 10 contiguous amino acids of the full length sequence set forth in SEQ ID NO: 1 and therefore the genus of nucleic acid probes comprising a nucleotide sequence that encodes a polypeptide comprising 10 contiguous amino acids of SEQ ID NO: 1 has been disclosed.

Applicants traversal is not found persuasive because while applicants have disclosed the claimed genus, applicants have not adequately described said genus.

Art Unit: 1652

Applicants have not disclosed a function of those molecules **comprising** a nucleotide sequence that encodes at least 10 contiguous amino acids of SEQ ID NO: 1.

As stated in the previous office action, applicants specification only provides a single representative species which encodes the FRS2 polypeptide having the amino acid sequence of SEQ ID NO: 1, encompassed by the claims. There is no disclosure of any particular **structure to function/activity relationship** in the disclosed species. The specification also fails to describe additional representative species of these nucleic acids by any identifying structural or functional characteristics. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

It is noted to applicants that claims 25-29 are included in this rejection for the reasons previously stated for the other claims in the rejection because each of these claims was interpreted as being drawn to the nucleic acid having each of the limitations corresponding with each of the respective claims (i.e. not including the limitation of claim 11 from which they depend) (See above 112 2nd paragraph rejection).

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 4-6, 22, 24 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a FRS2 polypeptide, wherein said FRS2 polypeptide has the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for any nucleic acid encoding any FRS2 polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applied to claims 2, 4-6 11-13 and 20-23. In response to the previous office action applicants have amended claims 11, 21 and 22 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection with respect to claim 4, on the basis that one of ordinary skill in the art would know how to use the nucleic acid probes of claim 4 and applicants cite various passages from applicants specification. Applicants refer to the use of those molecules that can detect nucleic acid molecules encoding a FRS2 polypeptide, however applicants are reminded that the currently claimed genus is not to those molecules that can detect nucleic acid molecules encoding a FRS2 polypeptide, but rather to any molecule which comprises a nucleotide sequence which encodes a mere 10 contiguous amino acids of SEQ ID NO: 1.

As discussed above, claims 25-29 are included in this rejection for the reasons previously stated for the other claims in the rejection and because each of these claims was interpreted as being drawn to the nucleic acid having each of the limitations

Art Unit: 1652

corresponding with each of the respective claims (i.e. not including the limitation of claim 11 from which they depend) (See above 112 2nd paragraph rejection).

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid encoding any polypeptide comprising a mere 10 contiguous amino acids of SEQ ID NO: 11. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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Application/Control Number: 09/731,660

Page 9

Art Unit: 1652

2/24/2004